



Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to sugar beet fibre and decreasing intestinal transit time pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to sugar beet fibre and decreasing intestinal transit time pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Nordic Sugar A/S, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Denmark, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim based on newly developed scientific evidence related to sugar beet fibre and “decreasing intestinal transit time”. The food constituent that is the subject of the health claim is sugar beet fibre. This opinion applies to sugar beet fibre naturally present in foods and to those forms added to foods. The Panel considers that sugar beet fibre is sufficiently characterised in relation to the claimed effect. The claimed effect is “decreasing intestinal transit time”. The target population proposed by the applicant is people who want to improve or maintain normal bowel function. The Panel considers that decreasing intestinal (orofaecal) transit time may be a beneficial physiological effect. The applicant provided four human studies as pertinent to the health claim. The Panel considers that no conclusion can be drawn from three studies for the scientific substantiation of the claim owing to methodological weaknesses whereas one human intervention study showed no effect of the consumption of sugar beet fibre on decreasing intestinal (orofaecal) transit time. In weighing the evidence the Panel took into account that one human study from which conclusions could be drawn for the scientific substantiation of the claim showed no effect of sugar beet fibre on intestinal (orofaecal) transit time. The Panel concludes that a cause and effect relationship has not been established between the consumption of sugar beet fibre and decreasing intestinal transit time. © European Food Safety Authority, 2011

KEY WORDS

Sugar beet fibre, intestinal transit time, orofaecal transit time, health claims

¹ On request from the Competent Authority of Denmark following an application by Nordic Sugar A/S, Question No EFSA-Q-2011-00971, adopted on 23 November 2011.

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SUMMARY

Following an application from Nordic Sugar A/S, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Denmark, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to sugar beet fibre and “decreasing intestinal transit time”.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The food constituent that is the subject of the health claim is sugar beet fibre. The term “sugar beet fibre” includes fibre derived from all plants of the species *Beta vulgaris* L. Sugar beet fibre contains hemicelluloses (22-32 %), pectins (22-29 %), cellulose (19-28 %), protein (5 %), ash (3 %) and moisture (7 %). The presence of both soluble and insoluble polysaccharides is roughly in a 2:1 ratio. This opinion applies to sugar beet fibre naturally present in foods and to those forms added to foods. The Panel considers that the food constituent, sugar beet fibre, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

The claimed effect is “decreasing intestinal transit time”. The target population proposed by the applicant is people who want to improve or maintain normal bowel function. From the information provided by the applicant with respect to the health relationship, the Panel notes that the claimed effect refers to a decrease in orofaecal transit time. The Panel considers that decreasing intestinal (orofaecal) transit time may be a beneficial physiological effect.

The applicant identified four human intervention studies as pertinent to the health claim. The Panel considers that no conclusion can be drawn from three studies for the scientific substantiation of the claim owing to methodological weaknesses whereas one human intervention study showed no effect of the consumption of sugar beet fibre on decreasing intestinal (orofaecal) transit time.

In weighing the evidence the Panel took into account that one human study from which conclusions could be drawn for the scientific substantiation of the claim showed no effect of sugar beet fibre on intestinal (orofaecal) transit time.

The Panel concludes that a cause and effect relationship has not been established between the consumption of sugar beet fibre and decreasing intestinal transit time.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health), which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA:

- The application was received on 01/09/2011.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- The scientific evaluation procedure started on 20/09/2011.
- During the meeting on 23/11/2011, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to sugar beet fibre and decreasing intestinal (orofaecal) transit time.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: sugar beet fibre and "decreasing intestinal transit time".

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of sugar beet fibre, a positive assessment of its safety, nor a decision on whether sugar beet fibre is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Nordic Sugar A/S, Langebrogade 1, PO Box 2100, 1014 Copenhagen K, Denmark.

Food/constituent as stated by the applicant

According to the applicant, the food constituent for which the claim is made is sugar beet fibre.

Health relationship as claimed by the applicant

According to the applicant, sugar beet fibre increases the lumen volume due to an increased amount of indigestible residue in the colon, improved water retention capacity of the residue, stimulation of microbiological growth and production of gas. Sugar beet fibre's physical properties also help to reduce the transit time due to modulating colonic motility either by mechanical or chemical stimulation by the products of fermentation. The applicant states that also the release of compounds trapped by the fibre, bile or fatty acids is mentioned in the literature.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "Sugar beet fibre decreases intestinal transit time".

Specific conditions of use as proposed by the applicant

According to the applicant, the pattern of consumption is over 7 grams per day. The proposed target population are people who want to improve or maintain a normal bowel function.

ASSESSMENT

1. CHARACTERISATION OF THE FOOD/CONSTITUENT

The food constituent that is the subject of the health claim is sugar beet fibre.

The term "sugar beet fibre" includes fibre derived from all plants of the species *Beta vulgaris* L. Sugar beet fibre contains hemicelluloses (22-32 %), pectins (22-29 %), cellulose (19-28 %), protein (5 %), ash (3 %) and moisture (7 %). The presence of both soluble and insoluble polysaccharides is roughly in a 2:1 ratio (Thibault et al., 2001).

The applicant markets sugar beet fibre under the brand name Fibrex® in the form of powder/grains with different particle sizes, coarse (not milled) form and coarse pulp grains pressed into flakes. The manufacturing process is described and stability data are provided.

This opinion applies to sugar beet fibre naturally present in foods and to those forms added to foods.

The Panel considers that the food constituent, sugar beet fibre, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

2. RELEVANCE OF THE CLAIMED EFFECT TO HUMAN HEALTH

The claimed effect is "decreasing intestinal transit time". The target population proposed by the applicant is people who want to improve or maintain normal bowel function.

From the information provided by the applicant with respect to the health relationship, the Panel notes that the claimed effect refers to a decrease in orofaecal transit time.

The Panel considers that decreasing intestinal (orofaecal) transit time may be a beneficial physiological effect.

3. SCIENTIFIC SUBSTANTIATION OF THE CLAIMED EFFECT

The applicant searched the databases MEDLINE, CAB Abstracts, Food Science & Technology Abstracts, and Foodline:Science fibre for beet fibre OR beet fibre AND intestinal OR intestine OR constipation OR bowel OR

gastrointestinal OR health OR healthy OR faeces OR faecal OR humans NOT pig OR rat OR mice. Internet was searched with Google for “sugar beet fibre” OR “sugar beet fibre” AND “bowel function” OR “fecal bulk” OR “stool weight” OR “transit time”. The applicant identified four human intervention studies as pertinent to the health claim.

One open label, one-arm, uncontrolled study (Giacosa et al., 1990) investigated the effects of sugar beet fibre on stool frequency and consistency in 27 subjects with chronic constipation. Intestinal transit time was not assessed. The Panel considers that no conclusion can be drawn from this study for the scientific substantiation of the claim.

One randomised cross-over study (Hamberg et al., 1989) assessed the effects of sugar beet fibre on mouth to caecum (orocaecal) transit time by measuring the interval between ingestion of the test foods and the initial rise in H₂ concentrations in breath. The Panel notes that this method does not allow a direct measure of orocaecal transit time. The Panel notes that orocaecal transit time represents only a small part of the total (orofaecal) transit time and that it does not provide information about orofaecal transit time. The Panel considers that no conclusion can be drawn from this study for the scientific substantiation of the claim.

In a randomised, parallel study, Cherbut et al. (1991) evaluated the effect of five types of fibre (wheat bran, sugar beet, maize, pea hulls, and roasted cocoa) with similar particle size on orocaecal and orofaecal transit time in 40 healthy volunteers (eight subjects per group). The Panel notes that orocaecal transit time represents only a small part of the total (orofaecal) transit time and that it does not provide information about orofaecal transit time. Each subject consumed one of the test fibres (up to 30 g/d) or a fibre depleted diet (<10 g/d) for 15 days each in a random order. Orofaecal transit time was measured using coloured plastic pellets. The Panel notes that the scarce information provided in the publication with respect to the methodology used for statistical analyses does not allow a scientific evaluation and that the level of significance for comparisons between interventions is not specified. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

In a randomised, cross-over study, Lampe et al. (1993) evaluated the effect of supplemental sugar beet and wheat fibre on faecal weight and intestinal transit time in 20 healthy men (20-40 years). Subjects consumed 20 g/d of either sugar beet fibre or wheat fibre for 30 days each after a 20-day run-in period during which all subjects consumed a self-selected diet providing about 22 g/day of dietary fibre. Subjects were asked to maintain their usual (self-selected) diet for the entire duration of the study. The Panel notes that this study does not have a washout period. Fibre supplements were consumed with meals. Faeces were collected from day 11 to day 20 of the run-in and each feeding period. Intestinal transit time was measured three times on each diet period using radio-opaque pellets. A total of 17 men completed the study and entered data analysis. It is reported that the effect of treatment was assessed by analysis of variance (ANOVA) for cross-over designs taking into account the three study periods (run-in, sugar beet fibre and wheat fibre) and their sequence. However, the Panel notes that the statistical analyses performed are not fully described. Results were expressed as mean intestinal transit time (average time needed to pass all pellets) and 80% transit (the time required for 16 of the 20 pellets to be excreted). No significant differences in relation to mean intestinal transit time or 80% transit were reported between sugar beet fibre and the run-in (self selected diet) periods. The Panel notes that this study does not show an effect of sugar beet fibre on intestinal (orofaecal) transit time.

In weighing the evidence the Panel took into account that one human study from which conclusions could be drawn for the scientific substantiation of the claim showed no effect of sugar beet fibre on intestinal (orofaecal) transit time.

The Panel concludes that a cause and effect relationship has not been established between the consumption of sugar beet fibre and decreasing intestinal transit time.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, sugar beet fibre, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

- The claimed effect is “decreasing intestinal transit time”. The proposed target population for the health claim is people who want to improve or maintain a normal bowel function. Decreasing intestinal (orofaecal) transit time may be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of sugar beet fibre and decreasing intestinal transit time.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on sugar beet fibre and “decreasing intestinal transit time” pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0311_DK). September 2011. Submitted by Nordic Sugar A/S.

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